

### **REMARKS**

Claims 1-13, 15-34 and 36-46 are pending for the Examiner's review, of which claims 8, 12-25, 30, 32, 34, and 41-45 are presently withdrawn from consideration. Claims 12, 26, and 36 are presently amended. Please note that citations to the specification of the present application herein are made to the published application for convenience.

Claims 8, 12-25, and 41 stand withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). The office action indicates that the claims are drawn to non-elected Species A because they require that the second articulating portion be mounted to the second contacting member. Claim 8 has been amended for clarity, and the withdrawal of claim 8 is respectfully traversed. As seen in Fig. 19, the second contacting member is mounted for pivoting with respect to the second contacting member. Consequently, claim 8 is properly drawn to the elected Invention I and Species H, and should be rejoined in the present application.

Independent claim 12 is amended to read on the embodiment of Figs. 18 and 19 of the present application. Applicant, respectfully submits that the amendment of claim 12 is supported by at least ¶¶ 41, 42, 44, and 59 of the present application, and therefore, does not add new subject matter. Further, Applicant respectfully submits that claim 12, as amended, is properly drawn to the elected Invention I and Species H. Dependent claims 13, 14, 16, and 25 are amended to be consistent with newly amended claim 12. Thus, Applicant respectfully requests that claims 12-19, 21, 22, 24, and 25 be rejoined.

In Applicant's response to the office action dated July 16, 2007, Applicant traversed the withdrawal of claims 23 and 39. In the office action dated March 17, 2008, claim 39 was rejoined but not claim 23. It appears that dependent claim 23 was not rejoined because of the new withdrawal of independent claim 12. Thus, in view of the amendment to claim 12, Applicant respectfully requests that claim 23 also be rejoined. Also, claim 34, which was previously withdrawn from consideration, was amended to depend from claim 12 in Applicant's response to the office action dated 07/16/2007. Again, in view of the amendment to claim 12, Applicant respectfully requests that claim 34 also be rejoined.

#### ***Claim Rejections Based on U.S. Patent No. 4,932,975 to Main***

Claims 1-7, 9-11, 21, 22, 25, 40 and 46 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,932,975 to Main ("Main"). The office action asserts that Main discloses an arthroplasty prosthesis comprising a first upper bone contact member 11, a

second lower bone contact member 11, a central articulation member that allows for pivotal and translational movement of each contact independently comprising a first articulation portion 20 that is in sliding contact with a second articulation portion, and a body prosthetic portion 22. Further, the office action asserts that the second articulation portion slides within the first portion and is held there by a screw.

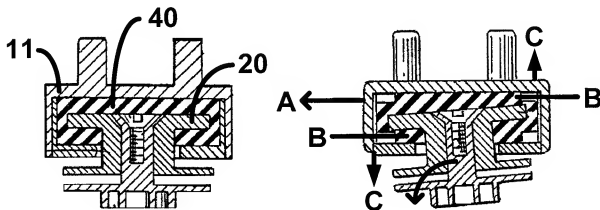
Applicant respectfully submits that independent claim 1 is patentably distinct from Main. Claim 1 recites, *inter alia*,

an articulation member supportively associated with the first and second contacting members to allow relative pivotal and translational movement therebetween . . . wherein the articulation member is configured to permit the translational movement substantially uncoupled from the pivotal movement.

Main fails to teach or suggest an articulation member that is configured to permit translational movement over anterior-posterior and lateral translational axes, as required by claim 1 (Taylor Declaration ¶ 6). Main states that the two housings 11 are secured against relative movement except to the extent allowed by axial movement, tipping movement, and limited torsional movement of suspension plates 20 in housings 11 (Main, 4:10-15). Pursuant to the statements made in Main itself, it allows relative translational movement of the housings 11 only along a vertical axis, i.e. extension and compression (Main 3:51-59). Because Main fails to teach or suggest relative translational movement of the housings 11 over anterior-posterior and lateral translational axes, it does not teach or suggest the invention of claim 1. Thus, claim 1 patentably defines over Main and is allowable.

Notwithstanding Main's explicit teaching, even if one were to improperly ignore this teaching and assume that translational movement of the housings 11 over anterior-posterior and lateral translational axes were possible, such movement would be coupled with pivotal movement, as opposed to claim 1 ("Taylor Declaration ¶ 7). Main teaches a prosthetic vertebral body including a pair of rigid housings, each of which includes a suspension plate 20 surrounded by an elastomeric medium 40. A connecting structure is rigidly attached to the plates 20. The outline of the plates 20 is slightly smaller than the cavity of the housings 11 to allow "a tipping action" as well as torsional movement of the plates 20 in the housings 11 (Main, 3:7-45), and compression and expansion along the spinal axis (Main, 3:45-59). The elastomeric material 40 functions as a suspending medium for the plate 20 within the housing 11 and exerts forces that restrain and cushion relative movement of the plate 20 and housing 11 (Main, 3:51-53).

Assuming lateral translational of the housings 11 were possible, any translation of housing 11 would cause plate 20 to rotate and would induce a bias against such rotation, indicating that the two movements are indeed coupled. For example, the figure on the left below shows the vertebral prosthesis of Main in a normal state. As shown in the figure on the right below, as housing 11 is biased for translation in direction A, plate 20 will rotate (Taylor Declaration ¶ 8). The rotation of plate 20 with respect to housing 11 will cause some parts of the elastomeric medium 20 to compress at locations B, as shown below (Taylor Declaration ¶ 8). Because the elastomeric medium 40 functions to restrain relative movement between housing 11 and plate 20, the elastomeric medium will exert torque tending to pivotally bias housing 11 with respect to plate 20 as shown by arrows C and restore the normal relationship between housing 11 and plate 20, as shown in the figure on the right below (Taylor Declaration ¶ 8). As shown in the figures below, any assumed translational motion of housing 11 in the device of Main would indeed be coupled to rotational movement of housing 11 and not substantially uncoupled from pivotal movement of housing 11, as recited in claim 1 (Taylor Declaration ¶ 8). Thus, claim 1 further patentably defines over Main and is allowable.



With respect to dependent claim 6, Main fails to teach or suggest an articulation member comprising first and second portions that are translatable with respect to each other along at least one of the anterior-posterior and lateral translational axes. The office action asserts that Main discloses a central articulation member comprising a first articulation portion 20 that is in sliding contact with a second articulation portion. Additionally, the office action asserts that the second articulation portion slides within the first portion and is held there by a screw. First, since this screw specifically fixes the two parts of Main, it thus, contrary to the claim, does not

allow the sliding in the prosthesis. Removing the screw would be contrary to the teaching and likely render the Main device unusable as a prosthesis. Second, even if one were to disassemble the Main device, removing housing 11, and extracting the plate 20 from the elastomer, which would likely destroy the elastomer, removing the screw would still not allow sliding because it is clear that the portion around the screw head has been flared out at the screw, and no longer allow sliding. So the alleged sliding could not happen even upon removal of the screw, and removing the screw would require disassembly such that the pieces are no longer associated as intended or required to function. Furthermore, the two suspension plates and the mass of hardened material within the bellows become firmly locked together when the core material has hardened or cured (Main 4:5-8). Further, there is nothing in Main to indicate that an upper portion of the suspension plate slides within a lower portion of the suspension plate. In fact, the drawings show that the upper and lower portions of the suspension plate are fixed together by a screw. Moreover, even assuming that the upper and lower portions of the suspension plate could slide with respect to each other, such sliding motion would be along a vertical axis and not one of an anterior-posterior or lateral translational axes, as defined in claim 6. Thus, dependent claim 6 further patentably defines over Main and is allowable.

With respect to claim 11, Main fails to teach or suggest an articulation member comprising first and second articulation portions articulably associating a body prosthetic portion with each of first and second contacting members, respectively. Although the housing structure 11 may articulate with respect to the plate structure 20, the plate structure 20 is fixed with respect to the connecting structure 22. The two suspension plates and the mass of hardened material within the bellows become firmly locked together when the core material has hardened or cured (Main 4:5-8). Thus, Main fails to teach an articulation member including two articulation portions that are articulably associated with a body prosthetic portion, as required by claim 11. Such an arrangement is shown in Fig. 19 of the present application and includes a pair of articulation portions 48, 49 forming articulation members, each allowing for uncoupled pivotal and translational movement. Thus, dependent claim 11 further patentably defines over Main and is allowable.

Applicant respectfully submits that independent claim 40 patentably defines over Main. Claim 40 recites, *inter alia*,

upper and lower articulation members, each comprising first and second articulation portions that are movably associated with each other, the first

articulation portion being pivotably associated with a respective one of the upper and lower disk prosthetic portions, and the second articulation portion being pivotably associated with the body prosthetic portion.

As explained above in connection with claim 6, Main fails to teach or suggest a articulation member comprising first and second articulation portions that are movably associated with each other. Further, as argued above in connection with claim 11, Main fails to teach or suggest a first articulation portion pivotally associated with one of an upper and a lower disk prosthetic portion, and a second articulation portion pivotally associated with a body prosthetic portion. Accordingly, claim 40 patentably defines over Main and is allowable.

Thus, Applicant respectfully submits that claims 1, 6, 9, 11, and 40 are allowable. As claims 2-5, 7, 9, 10, 21, 22, 25, 40 and 46 depend from 1, 6, 11, and 40, Applicant respectfully submits that they are likewise allowable.

***Claim Rejections Based on U.S. Patent No. 5,258,031 to Salib***

Claims 26-29, 31 and 33 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,258,031 to Salib ("Salib"). The office action asserts that Salib discloses an arthroplasty prosthesis comprising a first upper bone contact member 20, second lower bone contact member 22, central articulation members 24 and 44, and diagonally orientated first and second fastener mount holes 40. Further, the office action characterizes the Applicant's previous arguments regarding claims 26-29, 31, and 33 as arguments directed to intended use. Applicant respectfully disagrees and traverses the rejection.

Applicant's previous arguments were directed to functional limitations recited by claim 26 and not intended use. A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used (MPEP § 2173.05(g)). Claim 26 is presently amended to correct a typographical error and recites, *inter alia*,

vertebral contacting surfaces disposed and oriented for positioning an apophyseal ring of the first bone with respect to the fastener mount portion in an attachment position for attaching the fastener from the fastener mount portion through the apophyseal ring.

Thus, claim 26 recites that the vertebral contacting surfaces be disposed and oriented such that they perform the recited function (i.e. position the apophyseal ring with respect to the fastener mount portion such that a fastener may be attached from the fastener mount portion through the apophyseal ring). The apophyseal ring is a narrow mound that substantially encircles the upper

and lower surfaces of the vertebrae (Taylor Declaration ¶ 11). The apophyseal ring seldom extends more than a millimeter or two millimeters beyond the longitudinal range of the vertebra itself (Taylor Declaration ¶ 11). Fig. 3 of the present application shows an example of an appropriate position for a fastener mount portion for attaching a fastener from the attachment portion through the apophyseal ring.

Main does not teach or suggest base plates 28 and 48 that are capable of positioning the apophyseal ring of a vertebral body so that a fastener 42 can be attached from the tabs 30 and 50 through the apophyseal ring (Taylor Declaration ¶ 11). The mere fact that Salib shows diagonally-oriented first and second fastener mount holes does not mean that they are in a position for attaching the fastener through the apophyseal ring, as defined by claim 26. In fact, as explained in Dr. Taylor's declaration, the drawings clearly show the screws entering the bone well above the apophyseal ring (Taylor Declaration ¶ 11). Thus, claim 26 patentably defines over Salib and is allowable. As claims 27-29, 31 and 33 depend from claim 26, they likewise are allowable.

***Claim Rejections Based on U.S. Publication No. 2002/0183761 to Johnson***

Claims 36-38 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Publication No. 2002/0183761 to Johnson ("Johnson"). The rejection of claim 36 has been rendered moot by amendment. Claim 36 has been amended to depend from claim 1, which Applicant respectfully submits is allowable. Claims 37 and 38 depend from claim 36. Thus, Applicant respectfully submits that claims 36-38 are allowable.

***Claim Rejections Based on U.S. Patent No. 6,296,643 to Hopf***

Claims 39 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,296,643 to Hopf ("Hopf"). The office action asserts that Hopf discloses an arthroplasty prosthesis comprising an upper bone contact member 11, second lower bone contact member (bottom anchor figure 6a), a central articulation member (middle anchor figure 6a) that comprises holes for receiving suture 38.

Applicant respectfully submits that claim 39 patentably defines over Hopf. Claim 39 recites, *inter alia*,

first and second bone contacting members configured for engaging opposing articulated bones . . . an articulation member supportively associated with the first

and second contacting members to articulably associate the contacting members .  
.. and a suture.

As shown in Fig. 6a in Hopf, the top anchor and bottom anchor are not configured to engage opposing articulated bones while being connected to the middle anchor, as required by claim 39. Further, the middle anchor is not supportively associated with the top and bottom anchors, as required by claim 39. Instead, as shown in Fig. 6a in Hopf, each of the anchors is independently fixed to individual vertebra of the spine and are only connected by strand 38. Thus, claim 39 patentably defines over Hopf and is patentable.

### *Conclusion*

In view of the foregoing, the entire application is now believed to be in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues in an effort to expedite the allowance of this application.

Respectfully submitted,

Sept. 17, 2008  
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Date

  
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